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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,648	10/25/2001	Paul M. Sand	1759.17238-FOR	6512
26308	7590	08/05/2004	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			COOLEY, CHARLES E	
			ART UNIT	PAPER NUMBER
			1723	
DATE MAILED: 08/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,648	<b>Applicant(s)</b> SAND, PAUL M.	
	<b>Examiner</b> Charles E. Cooley	<b>Art Unit</b> 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 JUL 2004 has been entered.

***Drawings***

2. The formal drawings filed 9 JUL 2004 are approved but note the following objection:

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of new claim 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

If the subject matter of claim 17 is to be shown, corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8, 12-15, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Murray (US 5,348,391).

The patent to Murray (US 5,348,391) discloses a mixer comprising a receptacle 24 for receiving bone cement components, the receptacle having a distal tip (proximate 14); a mixing element 74 insertable into the receptacle; an actuator for the mixing element having a drive member 48 and a driven member 64 coupled to the drive member 48 and removably coupled to the mixing element (col. 4, lines 46-55); a stand 12 to hold the receptacle 24; the stand including a neck 14 sized and configured to couple to the distal tip of the receptacle (col. 3, lines 29-32 and col. 3, line 65 through

col. 4, line 1); the mixing element 74 being a rotatable apertured paddle rotated by the drive member 48 to mix the bone cement components; a plunger 26 insertable into the receptacle into the receptacle (see Fig. 1 which shows the discrete plunger 26 inserted into the receptacle 24) and the plunger advanceable through the receptacle through the action of a typical applicator to dispense the mixed material from the receptacle (col. 6, lines 43-49); a dispenser attachable to the receptacle to dispense the mixed bone cement (col. 6, lines 43-46); the actuator including a planetary gear drive train system (Figs. 1-2); linkage 38 between the drive member 48 and the driven member 64; and the drive member 48 being operable manually.

6. Claims 1-5, 8-12, 14-16, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (US 5,842,785).

The patent to Brown et al. discloses a mixer comprising a receptacle 1 for receiving bone cement components, the receptacle having a distal tip (proximate 3 in Fig. 1); a mixing element 5 insertable into the receptacle; an actuator for the mixing element having a drive member 7, 8 and a driven member 10 or 10' coupled to the drive member 7, 8 and removably coupled to the mixing element (col. 5, lines 54-63); a stand 13 to hold the receptacle 1; the stand 13 including a neck sized and configured to couple to the distal tip of the receptacle as seen in Figure 1; the mixing element 5 being a rotatable paddle with multiple apertures (as seen in Figs. 1 and 3 and col. 6, lines 17-18) rotated by the drive member 7, 8 to mix the bone cement components; a plunger 3 insertable into the receptacle into the receptacle (see Fig. 1 which shows the discrete plunger 3 inserted into the receptacle 1 and note col. 5, lines 13-15) and the plunger

advanceable through the receptacle through the action of a typical applicator 17 (Fig. 4) to dispense the mixed material from the receptacle (col. 6, line 63 through col. 7, line 4); a dispenser 12 attachable to the receptacle to dispense the mixed bone cement; linkage 100, 200 (Fig. 3A); the drive member 7, 8 being operable manually; the dispenser 12 being a nozzle or tube coupled to the distal tip of the receptacle (Fig. 4); the dispenser 12 having a fitting (the screw threads of Fig. 4) coupled to the distal tip of the receptacle 1; the plunger 3 including a proximal portion extending outside the receptacle 1 to advance the plunger as seen in Fig. 4.

7. Claims 1-4, 8-12, 14-16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hays et al. (US 5,549,381).

The patent to Hays et al. discloses a mixer in Fig. 10 comprising a receptacle 68 for receiving bone cement components, the receptacle having a distal tip 74; a mixing element 80 insertable into the receptacle; an actuator for the mixing element having a drive member 42 and a driven member 40 coupled to the drive member 42 and removably coupled to the mixing element 80; linkage 39 between the drive member and driven member (Fig. 11); a stand 11 to hold the receptacle 68; the mixing element 80 having rotatable paddles 91, 92 rotated by the drive member to mix the bone cement components; a plunger 72 insertable into the receptacle into the receptacle (see Figs. 15-16 which shows the discrete plunger 72 inserted into the receptacle 68 and note col. 7, lines 5-9) and the plunger advanceable through the receptacle through the action of a typical applicator (Figs. 15-16 and col. 22-27) to dispense the mixed material from the receptacle; a dispenser 75 attachable to the receptacle to dispense the mixed bone

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cement; the drive member 42 being operable manually; the dispenser 75 including a nozzle or tube 77 or 77A coupled to the distal tip of the receptacle (Fig. 16); the dispenser 75 having a fitting (the screw threads - col. 7, lines 15-19) coupled to the distal tip of the receptacle 68; the plunger 72 including a proximal portion extending outside the receptacle 68 to advance the plunger as seen in Figs. 15-16.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 5,348,391) in view of Seddon (US 5,494,349).

Murray discloses the mixing element with a single aperture and not a plurality of apertures. The patent to Seddon discloses a bone cement mixer of the planetary type wherein a manually driven mixing paddle 7 may have a single vane or multiple vanes with apertures between the vanes (col. 3, lines 11-18 and Figure 2). It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the mixing paddle of Murray with multiple vanes and corresponding apertures as disclosed by Seddon for the purpose of generating the most thorough mixing of the components (col. 3, lines 11-13).

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10. Claims 9-11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 5,348,391) in view of Chan (US 4,973,168).

Murray discloses a dispenser attachable to the receptacle to dispense the mixed materials as noted above but does not disclose the type of dispensers recited in instant claims 9-11 or the plunger including a proximal portion extending outside the receptacle to advance the plunger through the receptacle. The patent to Chan discloses a bone cement mixer having a mixing receptacle 7, 9 which includes a dispenser attachable to the receptacle to dispense the mixed materials. The dispenser comprises a fitting 120 attached to the distal tip (proximate 7) of the receptacle that includes a nozzle 121a, a tube 121b, or a pressurizer 140 (Figs. 10-12). The advanceable plunger 17 in the receptacle includes a proximal portion extending outside the receptacle to advance the plunger through the receptacle via applicator device 95 (Fig. 8). In view of the suggestion in Murray that the mixed bone cement is dispensed to an implant site via an applicator device (col. 6, lines 43-48), it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the mixer of Murray with a dispenser and a plunger proximal portion of the type taught by Chan for the purpose of adapting the dispenser to the particular type of operation being performed which is suitable for the particular opening of the implant site and to advance the plunger via the proximal portion of the plunger to inject the mixed bone cement into the implant site (col. 8, lines 59-63; col. 10, lines 34-52; col. 12, lines 55-58; col. 13, lines 48-56 and col. 14, lines 10-40).



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11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 5,348,391), Brown et al. (US 5,842,785), or Hays et al. (US 5,549,381) in view of Berg et al. (US 3,546,129) or Lorenz et al. (US 4,294,293).

Murray (US 5,348,391), Brown et al. (US 5,842,785), or Hays et al. (US 5,549,381) do not disclose the plunger having a valve. The patent to Berg et al. (US 3,546,129) discloses a plunger 44 with a valve member 52 therein. The patent to Lorenz et al. (US 4,294,293) discloses a plunger 78 with a valve member 88 therein. It would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have provided the plungers of Murray (US 5,348,391), Brown et al. (US 5,842,785), or Hays et al. (US 5,549,381) with a valve therein for the purpose of controlling flow of material through the plunger (Berg et al.: col. 6, lines 48-75 and Lorenz et al.: col. 6, line 65 through col. 7, line 3).

### ***Response to Amendment***

12. Applicant's arguments filed 9 JUL 2004 have been fully considered but they are not persuasive.

The member 26 in Murray is a piston or plunger (note the prior art uses these terms interchangeably and *Webster's New World Dictionary* defines "plunger" as "any cylindrical device that operates with a plunging motion, as a piston") that is insertable into the receptacle (the discrete plunger member must have been inserted into the receptacle 24 at some point to generate that which is shown and disclosed in Fig. 1 of Murray) and the plunger is clearly advanceable through the receptacle to dispense the

mixed material from the receptacle as suggested by col. 6, lines 43-49). In view of the noteworthy broadening of the claims, the prior to Brown et al. and Hays et al. clearly anticipates many of the pending claims as expressed in the rejections.

***Conclusion***

**13.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art shows piston or plunger members with valves.

**14.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles E. Cooley whose telephone number is (571) 272-1139. The examiner can normally be reached on Mon-Fri. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Charles", followed by a long, horizontal, wavy flourish.

Charles E. Cooley  
Primary Examiner  
Art Unit 1723

28 JULY 2004